APR 2 5 2014
K140834

510(k) Summary

Teratech Corporation

Terason™ uSmart3400 Ultrasound System

1. **Sponsor:**

Teratech Corporation
77-79 Terrace Hall Ave.
Burlington, MA 01803

Contact Person: Ben Chiampa,
Quality Assurance and Regulatory Affairs
Telephone: 781-270-4143

Date Prepared: March 21, 2014

2. **Device Name**

Proprietary Name: Terason™ uSmart3400 Ultrasound System
Common / Usual Name: Diagnostic Ultrasound System
Classification Name: Diagnostic Ultrasound Transducer

Ultrasonic Pulsed Doppler Imaging System
(21 CFR 892.1550, 90-IYN)
Ultrasonic Pulsed Echo Imaging System
(21 CFR 892.1560, 90-IYO)
Diagnostic Ultrasonic Transducer
(21 CFR 892.1570, 90-ITX)

3. **Predicate Devices**

Terason™ t3200 Ultrasound System (K110020)
Terason T3000 Ultrasound System with Needle Guidance (K112953).

4. **Intended Use**

The Teratech Corporation Terason™ uSmart3400 is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Pediatric, Small Organ

(thyroid, breast, testes), Neonatal Cephalic, Adult Cephalic, Musculoskeletal (conventional and superficial), Cardiac (adult and pediatric), and Peripheral Vascular.

5. Device Description

The Terason™ uSmart3400 ultrasound system is a portable, full-featured ultrasound system used to acquire and display high-resolution, real-time ultrasound data using multiple image modes. This system contains a proprietary ultrasound engine (identical to the predicate device Terason t3200 ultrasound system) for controlling the acoustic output of the transducer and processing the return echoes in real time. These data are then transferred to the host single-board computer (previously laptop computer) over a FireWire (aka IEEE 1394) connection for further processing and generation and display of the ultrasound image. Three transducers (15L4, 5C2A, 4V2A) connect to the system using the identical connector to the predicate device, Terason t3200.

The Terason™ uSmart3400 ultrasound EBook weighs 14.6 pounds and has a 15.3" backlit screen. The system dimensions (3.5"(H) x 15.3"(W) x 15.6"(D)) are chosen to allow the system to be hand carried. A Lithium-Polymer battery (integrated into the EBook) provides 2 hours of continuous ultrasound scanning. The system includes a medical-grade power supply (for charging). The ultrasound transducer connector is identical to that used in the Terason™ predicate device, the t3200. Optional accessories include a cart and printer.

6. Technology Characteristics

The design and construction of the Terason™ uSmart3400 is similar to the Terason™ t3200 and Terason™ t3000 systems. These systems utilize a laptop computer running Windows 7 to execute the ultrasound application and a custom designed engine for control of the acoustic array and processing of the return echoes. For the uSmart3400, the engine is housed in a compartment that is attached to the base of the single-board computer.

The similarity and difference between the Terason™ uSmart3400 and the Terason t3200 Ultrasound System (the predicate device) include the following:

- The engines are the identical with no modification in the custom beamformer chip that provides for improved filtering of the return signal for wider bandwidth and better resolution across the entire image field. The engine connector to the transducers is identical to predicate device t3200.

- The ultrasound application software has been modified to improve the user workflow and ease of use commensurate with a diagnostic medical ultrasound application.
- The main chassis, containing the single-board computer, replaces the laptop computer in the predicate t3200 and t3000 devices.

Transducers: The Terason uSmart3400 will support 3 transducers. These transducers have been previously cleared.

- 15L4: Cleared in 510k submission K110020 (January 20, 2011)
- 5C2A: Cleared in 510k submission K112953 (February 3, 2012)
- 4V2A: Cleared in 510k submission K112953 (February 3, 2012).

The following provides additional details of the three transducers, presented in this submission, that were previously cleared.

- 15L4: equivalent indications for use, frequency settings, shape of transducer head and needle guide/software brackets. Same manufacturer, same acoustic array and patient contact materials.
- 5C2A: equivalent indications for use, frequency settings, and needle guide bracket / software. Same manufacturer, same shape, same acoustic array and patient contact materials.
- 4V2A: equivalent indications for use, frequency settings, and needle guide bracket / software. Same manufacturer, same shape, same acoustic array and patient contact materials.

7. Table of Similarities and Differences Compared to the Predicate Devices

Terason uSmart3400 System and Transducers Comparison and Discussion
Previously cleared 510(k) transducers 15L4 (K110020) and 5C2A, 4V2A (K112953)

Terason uSmart3400

	Subject Device Model **Terason uSmart3400** **(This Submission)**	**Comparable Predicate Device** **Terason t3200** **(K110020)**	**Comparable Predicate Devices** **Terason t3000** **(K112953)**
Intended Use	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body	Diagnostic Ultrasound imaging or fluid flow analysis of the human body
Indication for Use	Fetal, Abdominal, Pediatric, Small Organ (Thyroid, Breast, Testes), Neonatal Cephalic, Adult Cephalic, Musculo-skeleltal (Convent.), Musculo-skeletal (Superfic.), Cardiac Adult, Cardiac Pediatric, Peripheral vessel	Fetal, Abdominal, Intra-operative (abdominal, thoracic and PV), Laparoscopic, Pediatric, Small Organ (Thyroid, Breast, Testes), Neonatal and Adult Cephalic, Trans-rectal and Trans-vaginal, Musculo-skel. (Convent.), Musculo-skel. (Superfic), Cardiac Adult, Cardiac Pediatric, Peripheral vessel	Fetal, Abdominal, Intra-operative (Spec.), Intra-operative (Neuro), Laparoscopic, Pediatric, Small Organ (Thyroid, Breast, Testes, etc.), Neonatal Cephalic, Adult Cephalic, Trans-rectal, Trans-vaginal, Musculo-skel. (Convent.), Musculo-skel. (Superficial), Cardiac Adult, Cardiac Pediatric, Peripheral vessel
Transducer Types	Linear Array Curved Array Phased Array	Linear Array Curved Array	Linear Array Curved Array Phased Array Endocavity – curved array Hockey Stick – Linear Bi-plane –Linear/curved
Acoustic Output and FDA Limits	Display Features for High Outputs	Display Features for High Outputs	Display Features for High Outputs
Global Maximum Outputs/Worst Case Setting	$I_{SPTA.3}$: 618.4 mW/cm^2 (15L4) TI Type: TIC (15L4) TI Value: 5.29 (15L4) MI: 1.75 (15L4) $I_{PA.3}$@MI Max: 970.6 W/cm^2 (15L4)	$I_{SPTA.3}$: 562.1 mW/cm^2 (15L4) TI Type: TIC (15L4) TI Value: 5.80 (15L4) MI: 1.70 (15L4) $I_{PA.3}$@MI Max: 1029 W/cm^2 (15L4)	$I_{SPTA.3}$: 678.1 mW/cm^2 (12HL7) TI Type: TIB (4V2A) TI Value: 5.6 (4V2A) MI: 1.5 (4V2A) $I_{PA.3}$@MI Max: 227.3 W/cm^2 (4V2A)
Modes of Operation	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion)	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion)	B-Mode Grayscale Imaging Tissue Harmonic Imaging M-Mode (motion)

	Anatomical M-Mode Color M-Mode Color Power Doppler Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision II Postprocessing	Anatomical M-Mode Color M-Mode Color Power Doppler Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision II Postprocessing	Anatomical M-Mode Color M-Mode Color Power Doppler Velocity Color Doppler Duplex/Triplex – Doppler imaging Pulsed Wave (PW) Doppler TeraVision I Postprocessing
PW Doppler	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF	Available for all transducers Triplex Mode B-Mode and PW Doppler High PRF
Transducer Frequency	2.0 – 15.0 MHz	2.0 – 11.0 MHz	2.0 – 10.0 MHz
#Transmit Channels	128 Channels	128 Channels	128 Channels
# Receive Channels	128 Channels	128 Channels	128 Channels
Acoustic Output Measurement Standard	NEMA UD 2-2004 NEMA UD 3-2004	NEMA UD 2-2004 NEMA UD 3-2004	NEMA UD 2-2004 NEMA UD 3-2004
DICOM	DICOM 3.0 Structured Reporting, Worklist - Image Viewer	DICOM 3.0 Structured Reporting, Worklist - Image Viewer	DICOM 3.0 Worklist - Image Viewer
Product Safety Certification	IEC60601-1 IEC60601-1-2 IEC60601-1-6 IEC60601-2-37	IEC60601-1 IEC60601-1-2 IEC60601-1-6 IEC60601-2-37	IEC60601-1 IEC60601-1-2 IEC60601-1-4 IEC60601-2-37
EMC	IEC60601-1-2 CISPR11 Class B	IEC60601-1-2 CISPR11 Class B	IEC60601-1-2 CISPR11 Class B
System Characteristics	**uSmart3400:** With integrated single-board computer weighs 14.6 pounds (6.62 Kg) 15.3" backlit screen. System dimensions (3.5"(H) x 15.29"(W) x 15.58"(D)). A Lithium-Polymer battery (integrated into the tablet) provides 2 hours of continuous ultrasound scanning. Uses a medical-grade power supply Data transferred to the tablet computer over a FireWire (aka IEEE 1394)	**T3200:** Laptop Computer and console weighs 10.5 pounds (4.8 Kg) 11.5" LED backlit display and keyboard. System dimensions (2.25"(H) x 14.35"(W) x 9.82"(D)). A Lithium-Polymer battery (integrated into the Laptop) provides 2 hours of continuous ultrasound scanning. Uses a medical-grade power supply Data transferred to the tablet computer over a FireWire (aka IEEE 1394)	**Terason T3000:** Laptop Computer weighs: 8.0 pounds (3.6 kg), LED backlit display and keyboard. Laptop dimensions (H): 2.5", (W): 13.8", (D): 11.0" A Lithium-Polymer battery, (integrated into the Laptop) provides 2 hours of continuous ultrasound scanning. Uses a medical-grade power supply Data transferred to the laptop computer over a FireWire (aka IEEE 1394)

15L4 Transducer

Key Features	Subject Device Model Terason 15L4 Transducer	Comparable Predicate Device Terason 15L4 Transducer	Same or Different
510(k) Number	K1XXXXX	K110020	n/a
Classification	ITX	ITX	**Same**
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3400) to image abdomen, small parts, musculo-skel and peripheral vascular regions.	The transducer is intended to be used with a conventional ultrasound system (Terason t3200) to image abdomen, small parts, musculo-skel and peripheral vascular regions.	**Same:** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same:** Safety requirements of IEC60601 are equally met. **Effectiveness:** Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Linear Array	Linear Array	
Acoustic Array Characteristics: **Element count...** **Center frequency...** **Element size (pitch x elevation)...** **Elevation focus...**	128 elements 7.5 MHz 0.3mm X 4.0mm 20mm	128 elements 7.5 MHz 0.3mm X 4.0mm 20mm	**Same:** element count. Acoustic characteristics have met safety guidelines of IEC60601-2-37.
Acoustic Output and Device Settings	Per acoustic output testing.	The transducer performance has been evaluated in the previous 510(k) filing	**Same;** acoustic output safety guidelines. Safety is not compromised. Effectiveness equal.

		(K110020).	
Patient Contact Material	The transducer uses Silicone SIM R1001 as a contact material.	The transducer uses Silicone SIM R1001 as a contact material.	**Same.** The 15L4 transducer consists of same patient contact materials as the predicate device. The safety of each device with respect to biocompatibility is equivalent.

Discussion:

The 15L4 uses a same acoustic array than the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.

The 15L4 transducer consists of same patient contact materials as the predicate device.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 15L4 transducer is substantially equivalent to the Terason 15L4 transducer (K110020) with respect to safety and effectiveness.

5C2A Transducers

Key Features	**Subject Device Model** **Terason 5C2A Transducer**	**Comparable Predicate Device** **Terason 5C2A Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K112953	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3400) to image Fetal,	The transducer is intended to be used with a conventional ultrasound system (Terason t3000) to image Fetal,	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human

	Abdominal, Pediatric and Peripheral vessel.	Abdominal, Pediatric and Peripheral vessel.	body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: Both arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Style:	Curved Array	Curved Array	
Acoustic Array Characteristics: **Element count...** **Center frequency...** **Element size (pitch x elevation)...** **Elevation focus...**	 128 3.5 0.5mm X 13.0mm 80mm	 128 3.5 0.5mm X 13.0mm 80mm	**Same in elevation** Safety and effectiveness unchanged from predicate
Acoustic Array	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K112953).	**Same.** As the predicate device and therefore has different acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	Silicone ABS	Silicone ABS	**Same.** The 5C2A transducer consists of same patient contact materials as the predicate device.

Discussion:

The 5C2A uses a same acoustic array than the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.

The 5C2A transducer consists of same patient contact materials as the predicate device.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 5C2A transducer is substantially equivalent to the Terason 5C2A transducer (K112953) with respect to safety and effectiveness.

4V2A Transducer

Key Features	**Subject Device Model** **Terason 4V2A Transducer**	**Comparable Predicate Device** **Terason 4V2A Transducer**	**Same or Different**
Device Classification	ITX	ITX	**Same**
510(k) Number	K1XXXXX	K112953	n/a
Indications for Use	The transducer is intended to be used with a conventional ultrasound system (Terason uSmart3400) to image Fetal, Abdominal, Pediatric, Cephalic and Cardiac.	The transducer is intended to be used with a conventional ultrasound system (Terason t3000) to image Fetal, Abdominal, Pediatric, Cephalic and Cardiac.	**Same.** The proposed transducer and the predicate transducer have the identical claim of imaging similar regions in the human body.
Acoustic Array Technology:	Piezoelectric elements	Piezoelectric elements	**Same.** Regarding Safety: Both

Acoustic Array Style:	Phased Array	Phased Array	arrays allow focused transmission and reception of ultrasound energy to enhance image quality within the region of interest.
Acoustic Array Characteristics: **Element count...** **Center frequency...** **Element size (pitch x elevation)...** **Elevation focus...**	 64 2.8 256 microns X 12mm 16.3mm	 64 2.8 256 microns X 12mm 16.3mm	**Same in elevation** Safety and effectiveness unchanged from predicate
Acoustic Array	The transducer imaging performance has been evaluated in an acoustic tank.	The transducer performance has been evaluated in the previous 510(k) filing (K112953).	**Same.** As the predicate device and therefore has different acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.
Patient Contact Material	Silicone Valox	Silicone Valox	**Same.** The 4V2A transducer consists of same patient contact materials as the predicate device.

Discussion:
The 4V2A uses a same acoustic array than the predicate device and therefore has same acoustic characteristics. To ensure proper safety guidelines are met, acoustic testing was performed per the IEC60601-2-37 standard.

The 4V2A transducer consists of same patient contact materials as the predicate device.

Based on the identical indications for use, technological characteristics and performance testing, Teratech Corporation, Inc. believes the Terason 4V2A transducer is substantially equivalent to the Terason 4V2A transducer (K112953) with respect to safety and effectiveness.

Terason uSmart3400 Computer

	Subject Device Model **uSmart3400**	**Comparable Predicate Device** **t3000** **(K112953)**	**Same or Different**
System Characteristics	**uSmart3400:** With integrated single board computer weighs 14.6 lbs (6.62 Kg) 15.6" backlit wide screen. Dimensions (3.5"(H) x 15.29"(W) x 15.58"(D)).	**t3000:** With laptop computer weighs 8.0 lbs (3.6 Kg) 11.5" LED backlit wide screen. Dimensions (2.5"(H) x 13.8"(W) x 11.0"(D)).	**Different.** Dimensions, weight and display.
	A Lithium-Polymer battery provides 1.5 hours of continuous ultrasound scanning. Data are transferred to the host computer over a FireWire (aka IEEE 1394).	A Lithium-Polymer battery provides 1.5 hours of continuous ultrasound scanning. Data are transferred to the host computer over a FireWire (aka IEEE 1394).	**Same.** Ultrasound engine, communication protocol and hours of continuous operation.

The computer has a different form factor, weight and display size. The hardware ultrasound engine already had all the necessary functions and features to support the 3 transducers. The hardware revisions of the ultrasound engine remain unchanged.

Accessories / Kits:

uSmart3400 Transducer	**Accessory Description**	**Manufacturer / Part #**	**FDA 510k Clearance #**
15L4	Biopsy Kit	Civco #612-085	K882383/A
15L4	Sterile Sheath	Civco #610-002	K970513

Conclusion:

The intended uses and features are consistent with the traditional clinical practices and FDA guidance for clearance of Diagnostic ultrasound systems and transducers. The uSmart3400 and predict devices both conform to applicable electric safety medical device standards with compliance verified through independent evaluation. The uSmart3400 and predicate devices both meet FDA requirements for track 3 devices, indications for use, biocompatibility similarities, and are manufactured using FDA GMPs and ISO-13485 quality systems. Teratech Corporation believes that the uSmart3400 ultrasound system is substantially equivalent with regards to safety and effectiveness to the predicate devices as noted above.

B1. Non Clinical Tests

The Terason™ uSmart3400 system has been tested for compliance to the following standards (with the corresponding report referenced for each standard).

- IEC 60601-1 Medical Electrical Equipment Part 1: General Requirements for Basic Safety.
    - Intertek Test Record Number 100825086BOX-002.

- IEC 62366, Medical Devices: Application of usability engineering to medical devices.
    - Intertek Project: 100825086BOX-005.

- IEC60601-1-6, Medical Electrical Equipment – Part 1-6: General requirements for safety– Collateral standard: Usability
    - Intertek Project: 100825086BOX-007.

- IEC 60601-1-2:2007, Medical Electrical Equipment – Part 1-2; General requirements for basic safety and essential performance – Collateral Standard: Electromagnetic compatibility – Requirements and tests
    - IEC60601-1-2 IEI Integration Corp. Test Report Number, CE130709D16.

- IEC 60601-2-37 / EN60601-2-37 Medical Electrical Equipment Part 2: Particular requirements for the safety of ultrasonic medical diagnostic and monitoring equipment.
    - Transducer Model 5C2A: Intertek Report Number IEC60601-2-37 uSmart3400 5C2A: 100825086BOX-004
    - Transducer Model 15L4: Intertek Report Number IEC60601-2-37 uSmart3400 15L4: 100825086BOX-006
    - Transducer Model 4V2A: Intertek Report Number IEC60601-2-37 uSmart3400 4V2A: 100825086BOX-003.

- NEMA UD 3 Acoustic Output Display
  Terason uSmart3400 Ultrasound System User Guide, Volumes 1 and 2 (16-3401 and 16-3402).

- Biocompatibility Tests, ISO 10993 Part 5 and Part 10
    - Biocompatibility reports for all transducers

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

April 25, 2014

Teratech Corp.
% Mark Job
Responsible Third Party Official
1394 25th STREET NW
BUFFALO MN 55313

Re: K140834
Trade/Device Name: Terason uSmart3400 Ultrasound System
Regulation Number: 21 CFR 892.1550
Regulation Name: Ultrasonic pulsed doppler imaging system
Regulatory Class: II
Product Code: IYN, IYO, ITX
Dated: April 01, 2014
Received: April 2, 2014

Dear Mr. Job:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

This determination of substantial equivalence applies to the following transducers intended for use with the Terason Usmart3400 Ultrasound System, as described in your premarket notification:

Transducer Model Number

15L4	5C2A	4V2A

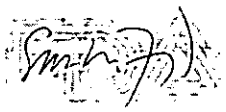
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director
Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See P R A Statement on last page.

510(k) Number *(if known)*
K140834

Device Name
Terason uSmart3400 Ultrasound System

Indications for Use *(Describe)*

The Teratech Corporation Terason™ uSmart3400 is a general purpose Ultrasound System intended for use by a qualified physician for evaluation by ultrasound imaging or fluid flow analysis of the human body. Specific clinical applications and exam types include: Fetal, Abdominal, Pediatric, Small Organ (thyroid, breast, testes), Neonatal Cephalic, Adult Cephalic, Musculoskeletal (conventional and superficial), Cardiac (adult and pediatric), and Peripheral Vascular.

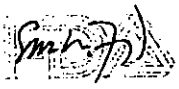
Type of Use (*Select one or both, as applicable*)

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over The Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (C D R H) (*Signature*)



Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3400 Ultrasound System

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	N	N	N		N	N	N
	Abdominal[d]:	N	N	N		N	N	N
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	N	N	N		N	N	N
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	N	N	N		N	N	N
	Neonatal Cephalic[d]:	N	N	N		N	N	N
	Adult Cephalic[d]:	N	N	N		N	N	N
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	N	N	N		N	N	N
	Musculo-skel. (Superfic)[d]:	N	N	N		N	N	N
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	N	N	N		N	N	N
	Cardiac Pediatric	N	N	N		N	N	N
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	N	N	N		N	N	N
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal, thoracic and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3400 – 15L4 Transducer

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]							
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Musculo-skel. (Superfic)[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal, thoracic and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P[1]: uses previously cleared under K110020

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Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3400 – 5C2A Transducer

Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:							
	Adult Cephalic[d]:							
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult							
	Cardiac Pediatric							
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E

[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.

[b] B+M; B+PWD; B+CD; B+DPD; B+PD.

[c] Harmonic Imaging (HI)

[d] Includes ultrasound guidance for placement of needles, catheters.

[e] Abdominal, thoracic and peripheral vessel.

[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy

[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.

[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.

Additional Comments: P[1]: uses previously cleared under K112953

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Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)

Indications for Use Form

510(k) Number (if known): _____

Device Name: Terason uSmart3400 - 4V2A Transducer
Indications For Use: Diagnostic ultrasound imaging system or fluid flow analysis of the human body as follows:

Clinical Application		Mode of Operation						
General (Track I Only)	Specific (Tracks I & III)	B	M	PWD	CWD	Color Dopp[a]	Comb. Modes[b]	Other[c]
Ophthalmic	Ophthalmic							
Fetal Imaging & Other	Fetal[h]	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Abdominal[e]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Intra-operative (Spec.)[d,e]							
	Intra-operative (Neuro)							
	Laparoscopic							
	Pediatric[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Small Organ (Thyroid, Breast, Testes, etc.)[d]:							
	Neonatal Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Adult Cephalic[d]:	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-rectal[f]:							
	Trans-vaginal[g]:							
	Trans-urethral							
	Trans-esoph. (non-Card.)							
	Musculo-skel. (Convent.)[d]:							
	Musculo-skel. (Superfic)[d]:							
	Intra-luminal							
	Other (Specify)							
Cardiac	Cardiac Adult	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Cardiac Pediatric	P[1]	P[1]	P[1]		P[1]	P[1]	P[1]
	Trans-esoph. (Cardiac)							
	Other (Specify)							
Peripheral Vessel	Peripheral vessel[d]:							
	Other (Specify)							

N= new indication; P= previously cleared by FDA; E= added under Appendix E
[a] Includes Color Doppler (CD), Directional Power Doppler (DPD), and (non-directional) Power Doppler.
[b] B+M; B+PWD; B+CD; B+DPD; B+PD.
[c] Harmonic Imaging (HI)
[d] Includes ultrasound guidance for placement of needles, catheters.
[e] Abdominal, thoracic and peripheral vessel.
[f] Includes ultrasound guidance for placement of needles, catheters, cryosurgery, and brachytherapy
[g] Includes ultrasound guidance of transvaginal biopsy, infertility monitoring of follicle development.
[h] Includes guidance of amniocentesis, infertility monitoring of follicle development.
Additional Comments: P[1]: uses previously cleared under K112953

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Concurrence of Center for Devices and Radiological Health

Prescription Use (Per 21CFR 801.109)